K050647

APR 20 2005



**Section 5**
**510 (k) SUMMARY**


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|---|---|
| Applicant: | Bisco, Inc.<br>1100 W. Irving Park Road<br>Schaumburg IL, 60193 |
| Contact Person: | Benjamin Lichtenwalner<br>Tel: 847-534-6146<br>Fax: 847-534-6111 |
| Date Prepared: | November |


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|---|---|
| Trade Name: | **ALL-IN-ONE** |
| Common Name: | Dental Adhesive |
| Classification/Name: | Resin Tooth Bonding Agent<br>**Class II per 21 CFR 872.3200** |

**Description of Applicant Device:**

As a Universal Self-Etching Adhesive System, ALL-IN-ONE Adhesive, as the name implies, is the only product one needs to etch, prime, and bond tooth structure. It is a two-component, single step adhesive system. ALL-IN-ONE is a light cure system that may be used for bonding both light-cure and self-cure composites, porcelain, and metal. ALL-IN-ONE may also be used for desensitization of tooth structures.

**Intended uses of Applicant Device:**

The principle uses of the ALL-IN-ONE Adhesive is to etch, prime, and bond for direct and indirect restorations involving dentin, enamel, light-cure and self-cure composites, amalgam/metals, porcelain, and core build-ups. ALL-IN-ONE can also be used for desensitization of tooth structures such as hypersensitive dentin/enamel and exposed root surfaces.

**Predicate Devices:**

Prompt L-Pop from ESPE Dental AG, cleared under K001494 dated May 9, 2000.

All-Bond 2 from Bisco, Inc, cleared under K910860 dated April 29, 1991.

## Section 5
## 510 (k) SUMMARY (continued)

**Significant Performance Characteristics:**

### PROMPT L-POP to ALL-IN-ONE

| Property | PROMPT L-POP | ALL-IN-ONE |
|---|---|---|
| Intended use | Self –Etching, Single Step Dental Adhesive | Self –Etching, Single Step Dental Adhesive |
| Chemical composition | Light-cure, unfilled, multifunctional methacrylate based resin. | Light-cure, unfilled, multifunctional methacrylate based resin. |
| Mechanical /physical properties | Low viscosity, yellow colored dental etching, priming, and bonding agent. | Medium viscosity, light pink colored dental etching, priming, and bonding agent. |

### ALL-BOND 2 SYSTEM to ALL-IN-ONE

| Property | ALL-BOND 2 SYSTEM | ALL-IN-ONE |
|---|---|---|
| Intended use | Multi-Step Dental Adhesive | Single Step Dental Adhesive |
| Chemical composition | Dual-cure, unfilled, multifunctional methacrylate based resin. | Light-cure, unfilled, multifunctional methacrylate based resin. |
| Mechanical /physical properties | Low viscosity, yellow colored dental etching, priming, and bonding agent. | Medium viscosity, light pink colored dental etching, priming, and bonding agent. |

Side by side comparisons of **ALL-IN-ONE** to the predicate devices **PROMPT L-POP** and **ALL-BOND 2 SYSTEM** clearly demonstrates that the applicant device is substantially equivalent to the legally marketed devices. **ALL-IN-ONE** was tested for oral toxicity and was found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **ALL-IN-ONE.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2005

Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K050647
Trade/Device Name: ALL-IN-ONE
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: March 11, 2005
Received: March 14, 2005

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K050647

Device Name: ALL-IN-ONE

Indications for Use:

As a Universal Self-Etching Adhesive System, ALL-IN-ONE Adhesive, as the name implies, is the only product one needs to etch, prime, and bond to a tooth structure and dental substrates.

ALL-IN-ONE is used for:

1. Direct restorations (composite, amalgam)
2. All indirect restorations (composite, metal, porcelain)
3. Desensitization of crown preparations prior to impression making/provisionalization
4. Composite core build-ups
5. Composite to metal/set amalgam (direct veneering)
6. Root desensitization
7. New amalgam to existing amalgam
8. Repairs (composite-to-composite, composite-to-porcelain)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number) K050647